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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,313	07/11/2001	Shuji Kitamura	4703/OJ586	2308

7278 7590 09/05/2002

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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/889,313

Applicant(s)

KITAMURA ET AL.

Examin r

Michael V. Meller

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-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The microorganism strain, *Lactobacillus helveticus* CM4 FERM BP-6060, is required to practice the claimed invention.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.

If the deposit(s) has/hav not been mad und r th Budapest Treaty, then to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registr. number, showing:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807;

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 9-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 583 074 (example 1, the claims, abstract, pages 2-3), Nakamura et al. (abstract, col. 3, example 1) or Yamamoto '940 (abstract, col. 1, col. 3, example 1).

The process is disclosed in the above references. The viscosity of the milk is inherent to the milk.

Claims 1, 3-5, 7, 9-13, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. '796 (see col. 1, example 1) or Yamamoto et al. '111 (col. 1, example 1).

The references teach the claimed process. The viscosity of the milk is inherent to the milk.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 583 074 (example 1, the claims, abstract, pages 2-3), Nakamura et al. (abstract, col. 3, example 1) or Yamamoto '940 (abstract, col. 1, col. 3, example 1).

The teachings of the references are above. They do not specifically teach that the specific strain *Lactobacillus helveticus* CM4 FERM BP-6060 is used, but it would have been obvious to use such a strain since such strains are well known in the art as is evidenced by the references. It is simply the choice of the artisan to use one strain over the others. The specific strain in the references would be expected to produce the same enzyme inhibitor as that produced by *Lactobacillus helveticus* CM4 FERM BP-6060. Thus, it is simply the choice of the artisan in an effort to optimize the results to use the specific strain, *Lactobacillus helveticus* CM4 FERM BP-6060 instead of the strain disclosed in the references.

Claims 1 and 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. '796 (see col. 1, example 1) or Yamamoto et al. '111 (col. 1, example 1) in view of JP 2782153 (abstract), EP 583 074 (example 1, the claims, abstract, pages 2-3), Nakamura et al. (abstract, col. 3, example 1) or Yamamoto '940 (abstract, col. 1, col. 3, example 1).

The teachings of the references are above. They do not specifically teach that the specific strain *Lactobacillus helveticus* CM4 FERM BP-6060 is used, but it would have been obvious to use such a strain since such strains are well known in the art as is evidenced by the references. It is simply the choice of the artisan to use one strain over

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the others. The specific strain in the references would be expected to produce the same enzyme inhibitor as that produced by *Lactobacillus helveticus* CM4 FERM BP-6060.

Thus, it is simply the choice of the artisan in an effort to optimize the results to use the specific strain, *Lactobacillus helveticus* CM4 FERM BP-6060 instead of the strain disclosed in the references.

To use a yeast along with the bacteria in the process would have been obvious since it is well known to use yeasts with bacteria to make ACE inhibitors as is documented by the secondary references. It is simply the choice of the artisan in an effort to optimize the desired results to add a yeast to obtain a superior ACE inhibitor product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. V. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Examiner
Art Unit 1651

MVM
August 28, 2002